

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

Plaintiff,

CENTER FOR ENVIRONMENTAL HEALTH,
PUBLIC EMPLOYEES FOR ENVIRONMENTAL
RESPONSIBILITY, and JAY DE LA ROSA,

Intervenor-Plaintiffs,

v.

INHANCE TECHNOLOGIES LLC,

Defendant.

Civil Action No. 5:22-cv-05055-JFM

**ORAL HEARING SCHEDULED
FOR 8/23/23**

**INHANCE TECHNOLOGIES LLC'S SUR-REPLY IN FURTHER
OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT**

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INTRODUCTION

In urging early resolution of this case, Plaintiffs have collectively filed reams of paper filled with technical jargon and complicated scientific assertions. That would not have been necessary if Plaintiffs' summary judgment claims were as strong as they suggest. There are a number of reasons that Plaintiffs are not entitled to summary judgment. Most principally: The Significant New Use Rule that forms the centerpiece of their claims does not apply to Inhance's fluorination process. Summary judgment at this stage of the case also is premature, particularly given the myriad disputed issues of fact and science.

The Government's claims are premised on a strained interpretation of the Toxic Substances Control Act (TSCA) and the agency's implementing Significant New Use Rule. Both sources of law prohibit manufacturers from engaging in a significant "new use" of a prohibited substance. But Inhance's fluorination process is anything but new. The Government now concedes this point, but nonetheless argues that the burden should have been on Inhance to raise its hand during the rulemaking process if it wanted to take advantage of an exemption for ongoing uses. That argument suffers from a fatal flaw: Inhance had no knowledge at the time of the rulemaking that its fluorination process generated PFAS. And the Government maintains that EPA did not, either. Gov. SJ Reply 9. Moreover, any PFAS generated during Inhance's fluorination process is subject to at least two relevant exemptions: one that governs impurities, and one that applies to articles. For all of these reasons, the Significant New Use Rule does not apply to Inhance's fluorination process, and the Government's claims should fail.

Enter the Intervenor. They seek summary judgment on different claims than the Government, but they lack standing, having failed to identify a cognizable injury that is fairly traceable to Inhance or that would be redressed by a favorable judicial decision. They also inject

into the litigation a host of cherry-picked, unvetted studies and reports penned by would-be experts—all before discovery has commenced. For all these reasons, their claims too should fail.

ARGUMENT

I. INHANCE IS NOT VIOLATING TSCA.

Inhance has explained since the beginning of this lawsuit that the Significant New Use Rule does not apply to fluorination of containers. That alone warrants immediate dismissal of all claims, with prejudice. At the least, though, Inhance is entitled to take discovery on a number of factual issues, including whether EPA considered fluorination of containers at the time it promulgated the Significant New Use Rule (SNUR), whether any PFAS generated by Inhance’s fluorination process are “impurities” exempt from the Rule, whether Inhance processes articles rather than chemical substances, and whether Inhance received fair notice that EPA might one day seek to apply the SNUR to its fluorination technology.

Plaintiffs argue that these are all legal questions. Gov. SJ Reply 14–15; Intervenor’s SJ Reply 5. They are not. At best, they are mixed questions of law and fact that the Court cannot resolve on the present record. *See Huang v. Attorney Gen. of U.S.*, 620 F.3d 372, 384 (3d Cir. 2010) (“A mixed question of fact and law is one that requires application of a legal standard to a particular set of circumstances.”). To resolve such mixed questions, the Court must make “case-specific fact-findings” before asking “whether those findings meet the specified legal threshold.” *Blackledge v. Blackledge*, 866 F.3d 169, 177 (3d Cir. 2017).

A. Inhance’s Fluorination Process Is Not A “New Use.”

First and foremost, it is now undisputed that the Inhance fluorination process is not a new use. That removes the Inhance fluorination process from the reach of TSCA. The statute authorizes EPA to regulate the manufacturing or processing of any chemical substance for “a use

which the Administrator has determined . . . is a *significant new use*.” 15 U.S.C. § 2604(a)(1)(A)(ii) (emphasis added). And under the agency’s implementing Significant New Use Rule, any uses that predate the publication of the proposed rule (i.e., January 21, 2015) are “ongoing” uses that do not require the submission of a Significant New Use Notice. Uses occurring after that date are deemed “new”—and thus subject to the Rule. *Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule*, 85 Fed. Reg. 45,190, 45,116 (July 27, 2020); ECF No. 49-2, A-58–75.

In its reply brief, the Government admits that Inhance’s use was ongoing as of that key date. *See* Gov. SJ Reply 14 (“[T]he United States does not dispute that Inhance has continuously fluorinated containers since before the Rule was proposed on January 21, 2015, and that such fluorination has produced long-chain PFAS throughout this period.”). That is a critical admission. Under the agency’s own interpretation of the regulation, Inhance’s use meets the definition of an ongoing use. Because a use that was ongoing cannot also be new, the Government cannot foist TSCA liability on Inhance. For that reason, not only should the Government’s and Intervenor’s motions for summary judgment be denied at this juncture, but dismissal of both Complaints is warranted, for the reasons spelled out in earlier briefing.

The Government argues that “any claim that EPA should have exempted fluorination from the Final Rule as an ongoing use is time barred” because it was not raised within 60 days of promulgation of the rule. Gov. SJ Reply 10. At that point in time, however, Inhance had no notice that EPA believed the rule even *applied* to the fluorination industry, so there was nothing for Inhance to challenge. In any event, the statute of limitations for challenging a rule does not apply in the context of an enforcement proceeding applying that rule. *See, e.g., Murphy Expl. & Production Co. v. Department of Lab.*, 270 F.3d 957, 958–959 (D.C. Cir. 2001); *South Hills Health*

Sys. v. Bowen, 864 F.2d 1084, 1094 (3d Cir. 1988) (“[U]nlike ordinary adjudicative orders, administrative rules and regulations are capable of continuing application; limiting the right of review of the underlying rule would effectively deny many parties ultimately affected by a rule an opportunity to question its validity.”) (quoting *Functional Music, Inc. v. FCC*, 274 F.2d 543, 546 (D.C. Cir. 1958)).

B. Inhance’s Fluorination Process Is Subject To The Impurity Exemption.

Inhance’s fluorination process also is exempt from the Significant New Use Rule because any PFAS generated in its process are “impurities” and thus subject to an exemption to the notice requirement. 40 C.F.R. § 721.45(d).

The regulations define “impurity” as a “chemical substance which is unintentionally present with another chemical substance.” 40 C.F.R. § 720.3(m).¹ Whether or not a substance constitutes an impurity thus hinges on a number of disputed factual issues, including whether the substance is unintentionally present with another chemical substance, whether the chemical substance is produced with a “separate commercial intent,” whether the chemical substance is produced during the manufacture, processing, use, or disposal of another chemical substance, *see* ECF No. 49-2, A-111 (EPA, *2020 Chemical Data Reporting Byproducts, Impurities, and Recycling Scenarios* (July 2020)), and whether the chemical substance remains part of—or is separated from—the intended product. *See* 40 C.F.R. § 721.45(e) (byproduct must be burned, disposed, or extracted (i.e., separated from the product) in order to be exempt).

The Government has not presented any evidence in support of its motion on any of these issues. Gov. SJ Reply 16. But contrary to the Government’s assertion, *id.*, Inhance *has* submitted

¹ EPA’s general SNUR regulations, 40 C.F.R. Part 721, state that the provisions of Part 720 apply to Part 721, so long as there is not a conflict between provisions. Part 721 does not include a separate definition of “impurity”; thus, the impurity definition as described in 40 C.F.R. § 720.3(m) applies.

evidence on these issues. Inhance submitted a declaration demonstrating that any PFAS generated in its fluorination process are “unintentionally formed and present within the exposed surfaces of plastic articles,” Iyer Decl. ¶ 23; “neither serve a functional purpose nor confer any commercial benefit on Inhance,” *id.* ¶ 24; are “not produced during the manufacture, processing, use or disposal of another chemical substance or mixture,” *id.* ¶ 20; and “cannot be separated from the fluorinated articles during the fluorination process,” *id.* ¶ 24. In sum, Inhance has consistently maintained that the long-chain perfluoroalkyl carboxylates (LCPFACs) are solely impurities that are exempt from the SNUR, 40 C.F.R. § 721.45(d), and the Government has failed to provide any legitimate rationale (much less evidence) to contest that understanding.

Instead, the Government points to the EPA submission form that Inhance filled out when completing its Significant New Use Notices (SNUNs), inviting the Court to surmise that Inhance somehow admitted to the agency that any LCPFACs are byproducts, not impurities. Gov. SJ Reply 17; *see also* Intervenor’s SJ Reply 6. Not so fast. Inhance has never conceded that the LCPFACs were byproducts. *See* ECF No. 50-2, A-24. Inhance has and continues to maintain that any unintentionally formed LCPFACs during fluorination are impurities, which are exempt from premanufacture notice requirements under EPA regulations. 40 C.F.R. §§ 720.30(h)(1), 721.45(d). EPA has stated that it believes the LCPFACs are byproducts. Although Inhance disagrees with EPA’s position, when filling out EPA’s premanufacture notice form, Inhance identified each LCPFAC species as both an impurity and a byproduct and included an explanatory statement clarifying that Inhance maintained its position that the LCPFACs were impurities and that its submission of the SNUN did not constitute a waiver of its impurity claim.

At minimum, discovery is needed to probe the Government’s position that LCPFACs generated by Inhance’s fluorination technology do not qualify for the impurity exemption. Gov.

SJ Reply 17–18. Among other things, discovery would illuminate whether EPA has historically considered impurities and byproducts mutually exclusive categories and whether EPA has previously determined impurities were not exempt from SNUR requirements because they were also unintended byproducts. *See, e.g.*, ECF No. 49-2, A-23–29. As EPA has affirmed, an “unintentional byproduct that remains with the intended product (i.e., is not isolated from that intended product) is an impurity.” EPA, *Q&A Document: Recycling and the TSCA Inventory of Chemical Substances Premanufacture Notification and Inventory Update Reporting Requirements* 8 (July 2010) (Exhibit 1). That is the case here.

C. Inhance’s Fluorination Process Is Subject To The Article Exemption.

There is another exemption that merits discovery as well. The Significant New Use Rule only applies if the technology is applied to a chemical substance rather than an article. 15 U.S.C. § 2602(13); 40 C.F.R. § 721.45(f). The containers fluorinated by Inhance readily meet the regulatory definition of an “article,” 40 C.F.R. § 720.3(c), and thus are exempt from the Rule.

The Government disagrees, arguing that the article exemption only applies if an entity “imports or processes” the chemical substance “as part of an article.” Gov. SJ Reply 23. It then proffers a daisy chain of definitions for words like “processes” and “preparation,” culminating in a Webster’s dictionary definition of the word “preparation.” *Id.* But any dispute over whether Inhance’s fluorination process does or does not involve an article is—again—a question of mixed fact and law that requires further factual development. *See Kotowski v. JGM Fabricators & Erectors, Inc.*, No. CV 18-1512, 2018 WL 11441014, at *1 n.1 (E.D. Pa. Aug. 13, 2018) (“The question of whether an exemption applies is a ‘mixed question of law and fact, requiring the Court to examine historical or record facts.’ ”) (quoting *Hively v. Allis-Chalmers Energy, Inc.*, No. 13-106, 2013 WL 2557629, at *2 (W.D. Pa. June 10, 2013)). Plaintiffs merely presuppose that the

facts will show that Inhance does not process a substance as part of any article. That factual claim should be tested; the Court should not take Plaintiffs' word for it.

D. Inhance Lacked Fair Notice Of The Government's Position.

The Significant New Use Rule also cannot be applied to Inhance because EPA never provided fair notice before the agency sought to enforce the SNUR against it. In the rulemaking itself, EPA identified a number of targeted industries, but said nothing about fluorination of containers. *See* 85 Fed. Reg. at 45,109; ECF No. 49-2, A-58.

The Government argues in response that the regulation broadly applies to "any use" that generates PFAS, regardless of the industry. Gov. SJ Reply 21–22; Intervenor's SJ Reply 7. But in the rulemaking process, EPA specifically identified at least 15 industries that were "potentially affected" by the rule. 85 Fed. Reg. at 45,110; ECF No 49-2, A-59. While the list did not purport to be exhaustive, it appeared under the heading "Does this action apply to me?" *Id.* The agency further explained that the list "provides a guide to help readers determine whether this document applies to them." *Id.* Not only was the fluorination industry not on the list, but the fluorination industry is not even *like* any of the industries that were on the list (*e.g.*, chemical manufacturing, petroleum refineries, carpet mills, and computer manufacturers).

There are other signs that the agency did not consider fluorination to be covered by the Significant New Use Rule. EPA performed an economic analysis supporting the rule, but did not even purport to evaluate the impact of the proposed rule on the fluorination industry. ECF No. 49-2, A-240–293. That would have been unlawful if the agency considered fluorination to be subject to the Rule. Indeed, EPA's own economic analysis of the Rule envisioned that very few entities would ultimately submit SNUNs. *Id.* at A-272 ("[F]ew, if any, entities are expected to submit a

SNUN. EPA has, over the years, promulgated SNURs that cover more than 1,000 chemicals. In response, the Agency receives only a handful of SNUNs per year.”).

The Government seems to suggest that EPA should be forgiven for these oversights because the agency did not know that fluorination created PFAS. Gov. SJ Reply 9. Well, neither did Inhance. The company thus lacked the factual predicate for understanding that the SNUR could have applied to Inhance. The Government tries to turn that fact on its head, suggesting that Inhance is nonetheless responsible for violating a law that it had no reason to know applied. Gov. SJ Reply 9. It would work a grave injustice—indeed, it would vitiate due process—for the Government to be able to enforce vague rules when neither the regulator nor the regulated industry had any knowledge that the laws were even triggered. This type of behavior is “deeply unsettling in a Nation built on the Rule of Law.” *PHH Corp. v. Consumer Fin. Prot. Bureau*, 839 F.3d 1, 48 (D.C. Cir. 2016) (cleaned up), *reh’g en banc granted, order vacated* (Feb. 16, 2017), *reinstated in relevant part on reh’g en banc*, 881 F.3d 75 (D.C. Cir. 2018). “The rule of law constrains the governors as well as the governed.” *Id.*

Plaintiffs’ briefs also give short shrift to TSCA’s peculiar regulatory scheme, in which EPA relies on *externally provided* information to structure Significant New Use Rules. What EPA knew about Inhance’s fluorination process before EPA issued the Rule—whether that information came from state administrative agencies, environmental nonprofits, the agency’s own prior investigations of Inhance facilities, or elsewhere—is relevant to Inhance’s affirmative defenses. If EPA considered fluorination activities at the time of the rulemaking but chose not to call them out in the rulemaking process alongside targeted uses, that would be highly relevant to the claims in dispute. Inhance should be given the chance to probe this issue in discovery.

The Government tries to resuscitate its position by suggesting that even if it failed to provide notice that the rule applied to Inhance at the time it was published, it did so later. Gov. SJ Reply 19. But the evidence is clear that Inhance moved fairly quickly to file SNUNs under protest, once it was finally on notice of the agency's position. The agency did not provide any warning to Inhance until it issued a notice of violation to the company years later, in March 2022, *see* ECF No. 49-2, A-223–225. It was not until yet another two weeks later that EPA issued an open letter to the industry asserting for the first time that the rule applied to fluorination. Iyer Decl. ¶ 38; ECF No. 49-2, A-227–228. Inhance moved quickly to perform risk assessments, obtain the necessary information to prepare its SNUNs, and submit the relevant notices, under protest, shortly thereafter. Iyer Decl. ¶¶ 39–40; ECF No. 49-2, A-23–29.

II. INTERVENORS LACK STANDING.

Inhance explained in its prior brief why Intervenorors lack standing. In response, Intervenorors suggest that they can simply piggy-back off of the Government's standing. Intervenorors' SJ Reply 1. Not so. The parties seek different relief on summary judgment: The Intervenorors seek injunctive relief, while the Government seeks declaratory judgment and suggests that the Court defer the question of injunctive relief until some later point in time. Gov. SJ Reply 24–25; Intervenorors' Response to Gov. SJ Reply 2–5. Thus, there is no pathway for the Court to address Intervenorors' request for injunctive relief without first addressing standing.

In response, Intervenorors rehash the facts alleged in the declarations of their members. Intervenorors' SJ Reply 2. But even a cursory review of the declarations shows that none of the declarants have demonstrated that they are (1) under threat of suffering a concrete and particularized injury; (2) the injury is traceable to Inhance's purported TSCA violations or alleged

delay in submitting a SNUN; and (3) the injury is redressable by granting Intervenor’s requested injunction. *See Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009).

As to injury, the declarants’ general “fear[] about the health impacts of using containers fluorinated by Inhance,” Intervenor’s SJ Reply 2, is insufficient to satisfy Article III’s injury requirement. *See Pennsylvania Prison Soc’y v. Cortes*, 508 F.3d 156, 166 (3d Cir. 2007) (“[A]llegations of injury at some indefinite future time—where the acts necessary to make the injury happen are within the . . . plaintiffs’ own control—lack the high degree of immediacy required to constitute injury in fact and provide Article III standing.”); *Public Int. Rsch. Grp. of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 120 (3d Cir. 1997) (Plaintiff’s “knowledge that [defendant] exceeded the effluent limits set by its NPDES permit does not, by itself, demonstrate injury or threat of injury.”).

Far from identifying the “specific plastic products to which declarants have been exposed,” Intervenor’s SJ Reply 2, the declarations contain only vague references to general categories of containers (e.g., “fast food wrappers,” “treated textiles,” “haicare bottles”) the declarants generally handle—they certainly do not establish that any such container was fluorinated by Inhance. *See* ECF No. 42-3 at A-7 (Bravo Decl.), A-10 (Sugarman Decl.). Without evidence proving that specific containers were fluorinated by Inhance and that those containers caused each declarant a “distinct and palpable injury,” Intervenor cannot satisfy the injury and traceability requirements of standing.

Because the Intervenor has not satisfied their burden of establishing that any of their individual members would have standing to sue, they do not have associational standing. *See American Chiropractic Ass’n v. American Specialty Health Inc.*, 625 F. App’x 169, 172 (3d Cir.

2015) (affirming dismissal of association’s claims for lack of associational standing because the association “failed to show that any of its members had standing in their own right”).

III. INHANCE IS ENTITLED TO DISCOVERY AND EXPERT TESTIMONY ON THE MANY DISPUTED ISSUES OF FACT AND SCIENCE RAISED IN INTERVENORS’ BRIEFS.

Intervenors’ briefs are replete with scientific assertions and expert opinions packaged as “facts.” Intervenors’ SJ Reply 3–4, 11–15. Inhance is entitled to test these expert opinions through discovery before they are accepted by the Court as fact on summary judgment. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 739 (3d Cir. 1994) (“[I]t is important that each side have an opportunity to depose the other side’s experts in order to develop strong critiques and defenses of their expert’s methodologies.”); *Lanning v. Southeastern Pa. Transp. Auth.*, 176 F.R.D. 132, 145 (E.D. Pa. 1997) (denying motion for summary judgment “as premature” where “expert discovery ha[d] not even started”); *United States v. Sunoco, Inc.*, 644 F. Supp. 2d 566, 582 (E.D. Pa. 2009) (same); *Coates v. Metropolitan Prop. & Cas. Ins. Co.*, No. CV 19-5143, 2020 WL 6220744, at *1 n.2 (E.D. Pa. June 11, 2020) (same).

Further, as Inhance pointed out in its prior brief, Inhance has been denied the opportunity to meaningfully respond to these studies because they were not attached to Intervenors’ opening brief. Intervenors took that criticism to heart, and produced some of the studies for the first time as a “Supplemental Appendix” to their reply brief—filed seven days ago. That is not a timely proffer of evidence, especially as it came after Inhance had already submitted its opposition brief. The studies therefore are not properly considered as part of Intervenors’ motion. *See Gucciardi v. Bonide Prod., Inc.*, 28 F. Supp. 3d 383, 393 (E.D. Pa. 2014) (summary-judgment reply “generally cannot be used to expand the issues presented for adjudication beyond those raised in the moving papers”).

IV. EQUITY DOES NOT FAVOR AN INJUNCTION.

Finally, an injunction is not an appropriate remedy here. Intervenor double down on their contention that the Court has no discretion in deciding whether to grant injunctive relief. Intervenor’s SJ Reply 9–11. Indeed, Intervenor posit that injunctive relief is the *only* remedy available to achieve compliance with TSCA, and that the Court “must” issue an injunction. Intervenor’s SJ Reply 9. The TSCA statute refutes this argument. 15 U.S.C. §§ 2615, 2616(a)(1)(A)–(D).

Intervenor’s argument against the Court’s equitable discretion also ignores Supreme Court and Third Circuit precedent. *See Chester ex rel. Nat’l Lab. Rels. Bd. v. Grane Healthcare Co.*, 666 F.3d 87, 95 (3d Cir. 2011) (noting the “high standard” required to overcome the presumption in favor of equitable discretion of the court). In *Oakland Cannabis Buyers*, the Supreme Court emphasized that the presumption in favor of equitable discretion is a very strong one, and can only be overcome where equitable relief is “textually required by any ‘clear and valid legislative command.’” *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 496 (2001). Intervenor have not shown a “clear and valid legislative command” that would overcome the presumption in favor of equitable discretion. This is because TSCA contains no textual requirement that a court grant prohibitory injunctive relief. *See Liebhart v. SPX Corp.*, 998 F.3d 772, 780 (7th Cir. 2021) (affirming district court’s denial of injunctive relief under TSCA, and explaining “[a]bove all, the issuance of injunctive relief [under TSCA] remains discretionary.”).

It is bad enough that Plaintiffs have put forward an ipse-dixit-like argument on liability. It is even worse that they try to carry this argument over into the remedy section of their brief. Plaintiffs have failed to articulate a basis for asserting that the public will be harmed absent an injunction pending appeal. While Inhance may be the only post-mold fluorinator in the United

States, there are other fluorinated containers in the market—many of them imported from abroad. An injunction will thus do little to protect Intervenor from their fears about PFAS exposure. In fact, the Government itself recognizes that “discovery is needed . . . regarding the risks to human health and the environment” purportedly caused by Inhance’s fluorination technology. Gov. SJ Reply 13 n.10.

On the other side of the ledger, Inhance will suffer devastating harm if an injunction is issued at this stage. Intervenor asks the Court to disregard those injuries as “purely speculative.” Intervenor’s SJ Reply 14–15. This is not speculation. It is fact. An order immediately suspending Inhance’s operations would massively disrupt both the company and multiple other critical industries. Iyer Decl. ¶¶ 8, 17–18. Not only would such an order effectively shutter Inhance’s business, but it would immediately cause supply chain disruptions across multiple industries. Iyer Decl. ¶¶ 17–18. Such irreparable and catastrophic harm weighs strongly against granting Intervenor’s requested relief. *See, e.g., South Camden Citizens In Action v. New Jersey EPA*, No. 01-2224, 2001 WL 34131402, at *1 (3d Cir. June 15, 2001) (“[T]he loss that the appellant will suffer as a result of its inability to operate its facility pending appeal cannot be compensated for by a money judgment.”); *Clean Ocean Action v. York*, 57 F.3d 328, 330 (3d Cir. 1995) (“catastrophic injuries to the shipping industry” that would be caused by injunction “outweighed the minimal or non-existent injuries to plaintiffs” even though defendants had likely violated ocean dumping regulations).

CONCLUSION

For all these reasons, the Court should grant Inhance's motions to dismiss and deny as moot Plaintiffs' motions for summary judgment. In the alternative, the Court should order a Rule 16 conference and defer or deny Plaintiffs' summary-judgment motions without prejudice to refiling at the time specified in the Court's scheduling order.

Respectfully submitted,

/s/ Virginia Gibson

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Dated: July 28, 2023

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